

K 974429

**510(k) Summary
RaPET® CRP**

FEB 18 1998

Submitter's Name

Kirk Johnson
Stanbio Laboratory, Inc.
2930 East Houston Street
San Antonio, TX 78202

Tel. (210) 222-2108
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Prepared By Kirk Johnson
November 14, 1997

Product Name

Trade Name: RaPET® CRP
Common Name: C-Reactive Test
Classification Number: 82DCN

Description of Device

The device test kit is comprised of CRP Latex Reagent, CRP Positive Control, Negative Control and Glycine/Saline Buffer for performing semi-quantitative testing.

Intended Use of Device

RaPET® CRP is intended for the qualitative and semi-quantitative detection of C-Reactive Protein in human serum. The latex slide test is intended to be used as an aid in evaluation of the amount of injury to body tissues.

^{CRP}
Comparison of Devices

Both ~~RF~~ latex methods employ latex beads coated with monospecific anti-human CRP (goat) which agglutinate in the presence of C-reactive protein serum.

Performance Data

Substantial equivalency was demonstrated by method comparison to Pulse's C-Reactive Protein Test. Correlation was performed between the two test kits with a correlation coefficient of 0.964 and a regression equation of $Y=0.93X + 0.36$.

In addition, precision, sensitivity, specificity, and interference studies were performed on RaPET® CRP. Results of these tests were found to be acceptable.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Kirk Johnson
Quality Assurance Manager
Stanbio Laboratory, Inc.
2930 East Houston Street
San Antonio, TX 78202

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 18 1998

Re: K974429
Trade Name: RaPET® CRP
Regulatory Class: II
Product Code: DCN 82
Dated: November 19, 1997
Received: November 24, 1997

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class-III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions.

Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

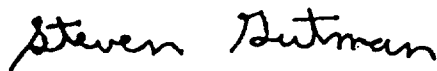
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,




Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974429Device Name: RaPET CRP

Indications For Use:

RaPET CRP (Class II) is intended for the qualitative and the semi-quantitative detection of C-Reactive Protein (CRP) in human serum. The latex slide test is intended to be used as an aid in evaluation of the amount of injury to body tissues.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974429

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)